Manufacturers Website

accessed 11/3/10

Problems of Diagnostics

Early detection of mammary gland pathologies has always been in the centre of medical community. The main reason being increased sickness rate of breast cancer and mortality resulting from it. Within the last 15 years breast cancer in the structure of oncologic pathology has shifted from the fourth place to the first. Every fifth woman dies due to breast cancer. Survival rate after treatments depends on the phase of the oncologic process. That is why early detection of cancer as well as other diseases of the mammary gland is prerequisite to reduction of death-rate among women.

Currently radiography of mammary glands and ultrasound examination are the principal methods of detection of mammary glands pathologies. Self-descriptiveness of mammary glands radiography is rather high in case the subjects of examination are glands with high amount of adipose tissue against the background of involution (sensitivity — 71-87%; specificity — 38%). But in case of young women with glandular structure of the mammary glands, so called radiologically "dense" glands, the degree of self-descriptiveness is reduced, becoming sometimes doubtful. Differential diagnostics between cysts and solid masses can□t always be relied on since some aggregate signs of malignant growths simulate a benignant process. Besides, radiography of mammary glands is connected with radiation, which is a contraindication in case of young women (under 30 years of age); in other age-groups it can be used only once in 1 — 1,5 years.

Self-descriptiveness of ultrasonic examination in differential diagnostics of malignant and benignant growths is rather high (sensitivity — 98%; specificity — 59%).). But the diagnostics accuracy depends on such factors as: the equipment model, user□s experience and professional skill, the patient□s age, her hormonal status, type and stage of disease.

Utilization of other methods — nuclear magnetic resonance, computed tomography scan, radionuclide diagnostics — can not considered always affordable due to high cost of examination.

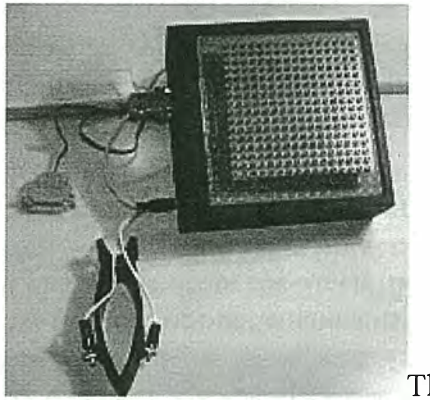
The abovementioned methods, offering high degree of resolution, make it possible to obtain images of the mammary gland. But inability to show changes of the gland structure in digital format doesn□t allow researchers and doctors to evaluate the objective state of mammary glands.

This is why a significant number of experts involved in diagnostics, treatment and follow-up care of cancer patients as well as patients suffering from other breast diseases, are faced with the task of discovering a new method for identification of breast pathologies, which would differ from the other existing methods by affordability, safety and level of information.

History of Device Creation

The works on development of electrical impedance tomography started in Russia in the 90s of the last century. A group of scientists from the Institute of Radiotechnology and Electronics of the Russian Academy of Science (director — an academician, professor, an honoured worker of science and technology, Doctor of Physico-Mathematical Science Guliaev Yu. V.) comprising Doctor of Science (Physics and Mathematics) Cherepenin V.A., Candidate of science (Physics and Mathematics) Korzhenevskiy A.V., Candidate of science (Physics and Mathematics) Kornienko V.A. and others in 1997 — 1998 were able to solve a mathematical problem of imaging internal tissues of human body utilizing electrical impedance tomography.

Their efforts resulted in development of a pilot model of the device for diagnostics of the mammary gland, which was later handed over to Karpov A.Yu,, doctor of the higher category, head of the perinatal department of the Clinical Hospital # 9 in Yaroslavl, whose painstaking work allowed him to develop medical basics of electrical impedance mammography.



The first variant of the diagnostic device was called “The Electrical Impedance computer Mammograph EIM-003 “Korvet”. The electrical impedance mammograph “MEIK” was covered by the patent of the Russian Federation No. 2153285 and No. 2127075, as well as the USA patent No. 6,167,300 and No. 6,236,886. The invention, which forms the basis of the device, was awarded a golden medal at the World□s Fair of Inventions in Brussels at the exhibition “Eureka '99”.

In 2003 PKF “SIM-technika” on the basis of the OAO “Yaroslavl Radio Works” set up commercial production and manufactured the first batch of the electrical impedance computer mammograph

"MEIK" (version 3.0).

The device underwent a successful period of testing and trials at the All-Russia Research Centre for X-ray and Radiology of the Ministry of Public Health in Moscow and at the Regional Oncology Centre of the 9th clinical hospital of Yaroslavl..

After obtaining the relevant approval documentation, starting from 2003 the electrical impedance mammography "MEIK"® has been used in medical practice at various medical institutions of Russia, the CIS, as well as in the countries of Europe and Asia.

Scientific and research work conducted by the PKF "SIM-technika" with involvement of mathematicians for the Yaroslavl State Demidov University as well as programmers and specialists in electronics from the Scientific and Production Enterprise "Spetspribor" enabled SIM-technika to start production from April 2007 of the 5th version of the device. This version differs from the previous modes by high degree of protection from noise and interference, perfect circuit design, high reliability in operation; in addition a fundamentally new software was developed as well, which was highly appreciated by doctors.

The electronics of the devices underwent principle alterations (the electrical circuit, isolation of printed circuit boards, power supply of active components; a block for preliminary filtration of signals from interference, noises and stray conductor-to-conductor flow of current; in addition, thanks to gold electroplating of the circuit boards and current-carrying parts, the jump potentials on the boarder of dissimilar metals was minimized).

As the production testing of the pilot batch of "MEIK"® proved, the abovementioned steps facilitated achievements of the following positive effects:

- 1. Elimination of noises and disturbances, which overlaying the main signal, led to deterioration of the obtain mammograms resolution capability, sometimes completely degrading the image.
- 2. Absence of need for calibration since stability of the obtained images and their numeric derivative characteristics are inbuilt into the electronic circuit itself.
- 3. Existence of independent channels (injecting and measuring) with individual power supply from the secondary sources DC-DC of the THI type with high insulation resistance and low level of interference make the device extremely reliable and electrically safe.

The software for the device (version 5.0) enables the user to perform the following:

- to monitor correct positioning of the electrode matrix on the breast;
- to control the procedure of measurement, data processing and archiving;
- to change the image parameters (colour scale, contrasting, noise filtering, image softening, a 3-D layer-specific image);
- to analyze electrical conductivity distribution, frequency distribution of electrical conductivity;
- to assist the doctor in the process of diagnostics (automatic prompting).

The Device Diagnostic Capabilities

The electrical impedance computer mammograph "MEIK"® 5th version" possesses high diagnostic capabilities, which can be realized during screening and early diagnostics of pathological diseases as well as diagnostic and treatment of nonpathological diseases. Mammograph "MEIK"® makes it possible to examine teenagers, women of any age, pregnant and breast-feeding women; it allows to diagnose breast cancer, mastopathy, mastitis, evaluate lactation function as well as monitor the state of the breasts during mastopathy treatment. Diagnostics of pre-cancerous (premalignant) conditions comprises one of the most important diagnostic capabilities of "MEIK"®. Due to the difference in electrical conductivity of malignant and healthy tissues existing from the initial stage of the tumour process, the device is capable of performing early detection of the oncology pathologies.

The advantages of the mammograph "MEIK"® are: safety for the patient and the staff, usability, convenience of the work site, absence of expensive disposables, financial affordability, live of delayed data transfer for obtaining professional advice and support, possibility for quantitative evaluation of the breast state.

Safety: the device possesses no contraindication, is non-invasive to patient and doctors, features no ration exposure due to lack of any radiation.

Convenient work site arrangement: the mammograph, the printer and the patient couch. There are no requirements concerning the premises, where the examination is conducted.

Absence of expensive disposables: Only disposable self-adhesive gel electrodes are used, which are similar to those used for the ECG.

Live of delayed data transfer for searching professional advice and support: The obtained results of examination can be easily E-mailed or sent vie internal computer networks. There is no need for installation of special software.

Possibility for quantitative evaluation: the mammography makes it possible not only to perform the visual evaluation of the breast state, but to obtain its quantitative analysis, which is significant in differential diagnostics of the mammary glands state and their pathologies.

The electrical impedance mammography is one of the key directions in development of electrical impedance tomography. The electrical impedance mammography is the method, allowing creating images of electroconductivity distribution of biological tissues in several cross-sections of the breast and detecting pathology on the images as an area with abnormal values of electrical conductivity.

Description and Principle of Operation

Electrical impedance computer mammograph.

The electrical impedance computer mammograph **MEIK®**, computing potentials, measured on the surface of the breast and the spacious distribution of the specific resistance (or electrical conductivity) in it, provides important information concerning its physiological and pathological processes, such as cancer, fibrous- cystous diseases, mastitis, physiological involution, lactation and so on. The measuring system and the algorithm of images reconstruction, used in the "MEIK"®, enable to visualize static distribution of electrical conductivity in the breast tissues, adjacent to the electrode surfaces. The measurement procedure is performed with the help of a matrix that comprises 256 electrodes. The current, passing through the breast tissues, creates a three-dimensional image of the electrical potential distribution. Data transmission and measurements occur simultaneously, and it takes about 35 second to perform the complete cycle of measurements. To reconstruct the 3-D distribution of electrical conductivity of the environment in the vicinity of the electrode matrix, the method of weighted back projections along the equipotential surfaces of electrical field is utilized. This method is a generalization of the back projection method, used in a 2-D electrical impedance tomography. The algorithm of back projection is used for reconstruction of 7 tomographic planes, passing through the breast tissues. The procedure of reconstruction lasts about 20 seconds. There are several options to additionally process the obtained images, offered by the software: numeric data filtration, colour scale, contrasting, highlighting of a specific area. In addition the computation comprises evaluation of mean electroconductivity, minimum and maximum values of the electroconductivity, standard deviation and modes; plotting of electrical conductivity distribution; comparative analysis with normal database; utilization of the renewed option “norm”.

MEIK® Version 5.0 Control menu

The mammary gland scanning and well as its qualitative and quantitative evaluation are controlled by the software. The screen display is conditionally divided into two fields: the field for operations with the image and the field containing control buttons. The control buttons are positioned in the left part of the screen and form blocks according to their functional criteria: the information block, the block for quantitative evaluation of the image, the block for information transfer (Fig. 1.)

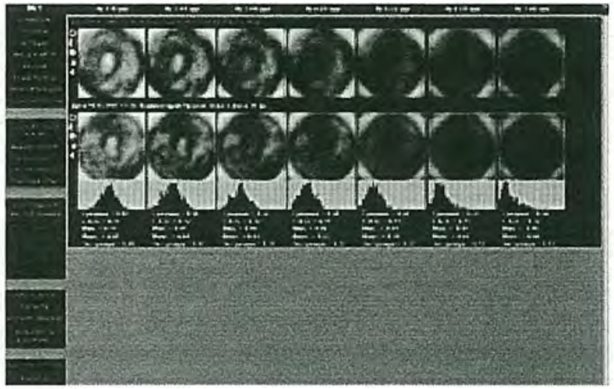


Figure 1. The field for image operation and the field with control buttons.

MEIK® Version 5.0 Data accessing

After completion of the breast scanning, seven images of it appear in the field, intended for image processing, corresponding to the scanning planes,

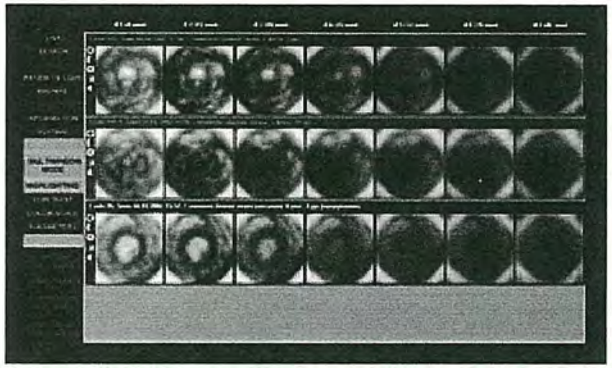
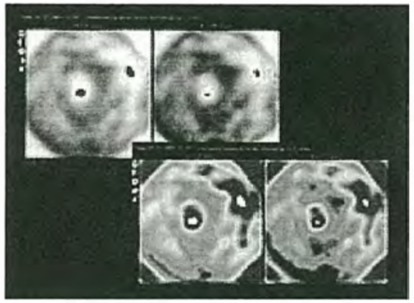


Figure 2. Seven scanning planes of the breast image.

which are parallel to the plane of the electrodes positioning, with depth of scanning increasing from 4 to 46 mm (Fig. 2). For additional processing of the obtained images there are several options, in form of “icons”, which can be seen to the left of the images: a colour scale, contrasting, highlighting of a specific areas, histrograms (Fig. 3).



MEIK® Version 5.0 Data evaluation

Computation comprises the index of mean electrical conductivity, maximum and minimum electrical conductivity, standard deviation and modes. Simultaneously plotting of the electrical conductivity distribution is performed. There is a possibility to compare the obtained data with the "norm" and calculate the nonparametric statistical algorithm of Kolmogorov-Smirnov — percentage of spread in the electroconductivity distribution. Comparison of the electroconductivity of the left and right breast can be carried out with calculation of the percentage of spread in the electroconductivity distribution (Fig. 4).

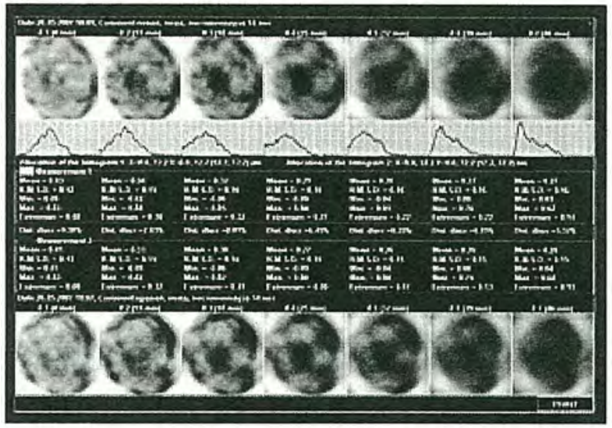


Figure 8. Comparison of the electroconductivity of the left and right breast with calculation of the percentage of spread in the electroconductivity in [illegible]

Comparison with other methods of visualization

Utilization of the electrical impedance method for the breast disease diagnostics requires development of special equipment and mathematical methods, which differ from those used in conventional systems for visualization. There are several significant technological differences in electroimpedance computer mammograph when the latter is compared with other methods of visualization, for instance, X-ray and nuclear magnetic resonance (NMR) tomography as well as the ultrasound study. Firstly, in case of the MEIK, weak alternative current (50 KHz, 0,5mA) is used as a probing environment; the device□s sensors register distribution of the electrical potential, caused by passing of the current via the examined media. The second difference is that in case of electroimpedance method the source of energy and the registering sensors are positioned on one plane. In the X-ray tomography, on the other hand, the emitter and the receiver are placed on different planes and are connected with each other by straight equipotential lines, crossing the visualized volume. In electroimpedance mammography the equipotential lines, along which the back data projection is performed, are curved. It makes is possible to perform the tomographic visualization while positioning the electrodes on the body surface without covering it from all sides (Fig. 5).

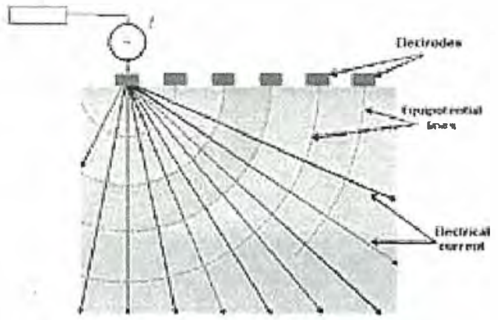


Figure 5. The current propagation paths and the equipotential lines.

The third principle different lies in the fact that the electroimpedance mammography enables the researcher to obtain a qualitative evaluation of the breast state, computing its mean electrical conductivity and the histrogram of the electroconductivity distribution in the breast. It makes it possible to perform an objective evaluation of the breast state and its comparison with the norm.
And in the forth place, it offers safety, convenience and self-descriptiveness of examination.

Clinical application

The electrical impedance can be utilized in the whole range of the breast diseases, namely: benign and malignant neoplasms, mastopathies, mastitis and so on. In addition electrical impedance can be used for dynamic monitoring of women, comprising a risk group, in order to check efficiency of treatment. This method of screening is widely used for women who take oral contraceptives and undergo substitutive hormonotherapy in climacterical period.

Oncology. The course of the oncological process development is accompanied by changes in electrical properties of the tumour itself as well as of the surrounding tissues. This phenomenon can be used for detection and localization of tumours. It is principally important for detection of noncomplicated forms of the disease, characterized by high electrical conductivity of malignant cells (figure 6) and complicated form of the disease, characterized by high local or general impedance (figures 7 and 8).

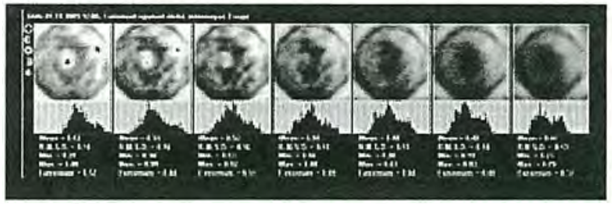


Figure 6. Noncomplicated forms of breast cancer

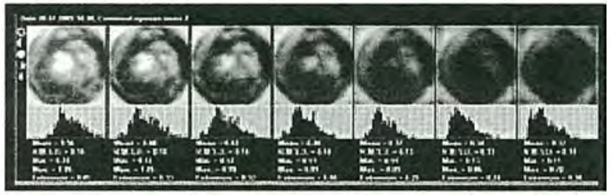


Figure 7. Complicated forms of breast cancer

Figure 8. Edematous-infiltrative form of breast cancer.

The method of electroimpedance mammography can be successfully used for screening, meeting the needs of any physician, as well as for any other diagnostic examination.

Mammology. According to the definition of the World Health Organization (Geneva, 1984) mastopathy is a mammary dysplasia, a fibro- cystic disease, characterized by a wide spectrum of proliferative and regressive changes of the breast tissues with abnormal ratio of epithelial and connective components. Since the quality and the ratio of the main tissue elements, such as, the cells of the duct and alveolar epithelium, collagen and elastic fibres, cells of adipose tissue, the main substance of the connective tissue define the physical and chemical properties of the breast, it would be logical to use the electrical impedance tomography of the breast for mastopathy diagnostics and monitoring of the treatments (figure 9).

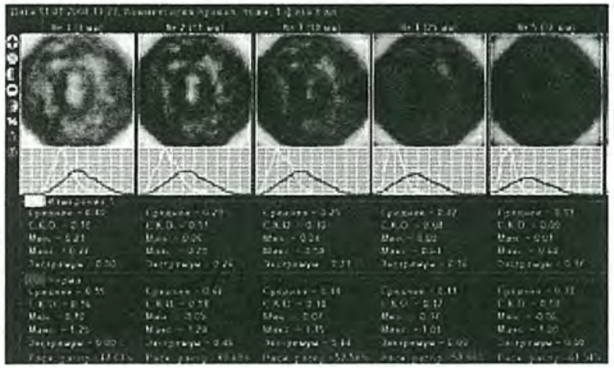


Figure 9. Mastopathy, fibrous form (compared with norm).

42

Obstetrics. The inflammatory process in the breast develops in the areolar tissue and is accompanied by a number of vascular changes with exudation of the liquid parts of plasma, emigration of blood cells and proliferation of stroma cells. When the inflammatory process develops the electrical conductivity of the inflammatory focus changes (figures 10, 11, 12).

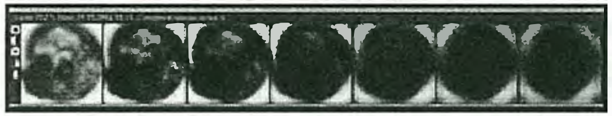


Figure 10. Mastitis. Infiltration stage

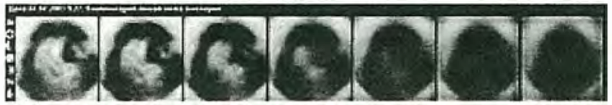
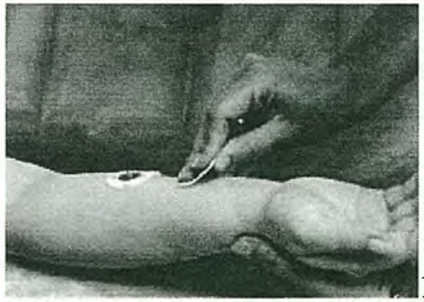


Figure 11. Mastitis. Abscess forming stage

Figure 12. Mastitis. Proliferation stage. Scarring

Device Operation

MEIK Version 5.0


1. Attach the disposable gel electrodes on the inside of the patient□s wrists of the hand nearest to the breasts to be examined. The distance between the electrodes should be within 1,5 — 2 centimetres.


2. Snap the leads with the clamps on the electrodes.

3. Evenly moisten the breast with wad of cotton wool soaked with water. Formation of droplets should be avoided.

97


4. Place the panel with electrodes (microprocessor transducer) against the breast in such a way that the laser marker is positioned on the nipple.


5. It is necessary to achieve a maximum number of good contacts on the "dynamic map of contacts".

6. To start the process of measurements, press the button “Start”. The panel with electrodes (microprocessor transducer) should be held to the breast not longer than 35 second.

7. After computer reconstruction of the image, evaluate the mammogram□s quality. In case of necessity the procedure should be repeated.

Technical Characteristics

The overall dimensions — 180x160x10 mm
Weight 2 kg
The current used for scanning is within the range of 0,5 mA ± 20%, frequency 50 kHz.
The mammograph can be operated non-stop during 8 hours under constant load.
The warranty period is 2 years from the moment of purchasing.
Average life — not less than 5 years.
The mammogrph has been manufactured in the climatic conditions that correspond to UHL category 4.2 in respect of GOST 15150 (State standard).
The electrical safety of the device meets the requirements of GOST R50267.0, second class of protection, type C.

Operational characteristics:

- Sensitivity - 92%,
- Specificity - 99%,
- Prognostication of positive result - 73%,

- Prognostication of negative result - 99%.

The length of examination procedure is 35 seconds.

The process of diagnostic examination from the moment of obtaining the case history to establishing a conclusion amounts on average to 15 minutes.

Screening examination lasts 3 — 5 minutes.

Before the software installation make certain that the computer meets the following requirements:

- Processor Intel Pentium IV and over (or compatible);
- Main memory — not below 512 Mb;
- Hard disk free space not below 500 □B;
- Available USB port;
- Video display card, supporting the mode of hardware acceleration 3D 128 MB or over;
- Operational system — WINDOWS XP with SP2;
- The computer display size — not below 15 inches.

Approval Documentation

The device has been recommended for commercial production and application in medical practice by decision of the "Commission for Equipment and Technical Facilities, Used in Oncology and Medical Radiology" of the Committee for new medical equipment of the Ministry of Public Health of the Russian Federation (registration certificate # 29/05010303/5420-03 of July 03, 2003). OKP 944220, class 2b, license for production of medical equipment (Registration number 64/2003 — 0328-0388 of 25.08.2003).

The mammograph "MEIK"® has a certificate of conformity # ROSS. RU.IM 02B14247 of the Gosstandard (State Standard) of Russia of October 02, 2006, the sanitary-hygienic decision # 77.99.34.944.D.007393.08.06.

Production of the electroimpedance mammograph "MEIK" has been certified as per the quality management ISO 9901 (with a certificate IQNet issuance) and ISO 13485.

In August - November 2007 "MEIK"® (5th version) underwent certification tests in the company ITC (affiliate office in Bratislava, Slovakia), which resulted in obtaining the European Certificate. This certificate grants the right to put the **CE 1023** mark during the process of manufacture.

The OOO PKF "SIM-technika" caries out patent protection of its new developments and designs. For instance, the design of the contact electrode of the microprocessor transducer matrix is an advanced and complicated construction, manufactured on the basis of precision technologies of a watch factory; it has been protected with the patient of RF # 48743 with priority from April 28, 2005.

The electroimpedance mammograph "MEIK"®. (5th version) has been protected by the patient of the RF for a useful model # 66932.

The software of the 5th version of "MEIK" underwent the process of official registration and has been entered into the Russian register of software for computers (certificate # 2007610436, registration date - January 25, 2007).

The trademarks: the logo "SIM-technika" and "MEIK" are registered trademarks and are property of the OOO PKF "SIM-technika".

Customer Support

The OOO PKF "SIM-technika" runs training courses for those who are interested in operating the electroimpedance computer mammograph "MEIK"®. The courses are organized at the centre of training and method learning at the facilities of the 9th clinical hospital of Yaroslavl. The training course lasts from 7 to 14 days depending on the computer literacy of the trainees. The cost of training in included into the cost of the device (travelling expenses and lodging are exclusive).

The curriculum of the course comprises following:

1. Electrical current and electrical conductivity of biological tissues.
2. Anatomy, histology and physiology of a mammary gland.
3. Electroimpedance anatomy of a mammary gland.
4. Procedure of electroimpedance scanning of mammary gland.
5. "MEIK". Principles of operation. Software.
6. Electroimpedance measurements at various physiological states.
7. Electroimpedance measurements at mastopathy.
8. Electroimpedance measurements at mammary gland inflammation.
9. Electroimpedance measurements at benign tumours of mammary gland.
10. Electroimpedance measurements at malignant tumours of mammary gland.
11. Practical classes on mammography.

The OOO PKF"SIM-technika" is ready to give advice and support in evaluation and interpretation of the mammograms in complicated clinical cases, vie E-mail or any other means of communication.

Any issues not covered by the information of our site or in case of queries, which occurred during practical application of the mammograph "MEIK"®, your can enter them into the space provided HERE or send to the following address: sim-tech@impedance.ru

The experts of PKF"SIM-technika" will deal with your questions in the shortest possible time.

Research and ~~Support~~ Development

From the moment of SIM-technika establishment its medical department has been conducting a versatile complex of scientific research activity directed at perfection of diagnostics technique based on the already developed devices, as well as at creating new methods and approaches. The results of their activity were made available at a number of international conferences (the last one held in Austria, Graz - ICEBI 2007, August - September, 2007) and were published in medical scientific journals. Since 2003 the work for two Ph.D. theses was completed, which were later defended with participation of experts from the medical departments of SIM-technika. Consequently the scientific degree of the candidate of medical sciences in the field of electroimpedance mammography and tomography was awarded.

The medical department of SIM-technika developed and published the "Atlas of the mammary gland electrical impedance images" and the "Album of selected electrical impedance images of the mammary gland" and "Methods for electrical impedance images evaluation". Both publications are of great help to practicing doctors.

Serious attention is paid to the copyright protection of various developments resulting from scientific and production activity of SIM-technika. Experienced specialists of the law firm "I.P.Pro" in Moscow render significant assistance in this respect.

The System of Quality Management ISO 9001 and ISO 13485 have been implemented at the company and are constantly monitored; this achievement has a positive effect on the product quality. Systematic work devoted to elimination of engineering drawbacks and technological imprecision has improved the technical parameters of "MEIK"® (5th version) — not only the device stability has improved; the quality of its diagnostic capabilities has increased as well. The comprehensive certification procedure of the electroimpedance computer mammograph "MEIK"® (5th version), carried out by the "Institute for Testing International" (Czech Republic, Zlin) jointly with the Slovak firm "Polyx Trade International s.r.o" has confirmed the above statements. The inspection of the company□s production facilities, performed after the certification, made it possible to put the CE mark at the production stage.

3d-Impedance Scanning Of The Breast Cancer - Chicago 2000

3d Eit System For Breast Cancer Detection (Phmeas3r)

Clinical Application Of Eit System For Static Imaging Of Tho

Electrical Conductivity Of Lungs And Respiratory Volumes In

Electrical Impedance Anatomy Of The Mammary Gland

Electric Impedance Measurements In Inferior Limbs Of The Pre

Electro-Impedance Mammography Testing At Some Physiological

Electroimpedance Measurements Of Pregnant Women With Big And

Electroimpedance Measurements Of Women

Functional Aspects Of Early Postnatal Developments

Particularities Of Electrical Impedance Images In Different

Preliminary Absolute Eit Images Of The Thorax In Health And

Procedure For Assessment Of The Mammary Gland Electrical Imp

Static Eit-Images Of Newborns□ Lungs. Preliminary Results

Questions and Answers

1. What forms the basis for the impedance mammography in diagnostics of breast disease?

A living organism does not only generate bioelectricity, but passively conducts the current, which occurs in it or is applied from outside. Electrical conductivity depends on the histological structure of the organ, its molecular and, finally, its elementary composition (structure and number of free electrical charges, their mobility). Electrical properties of many malignant formations considerably differ from the healthy tissues, surrounding them. If X-ray and ultrasound methods of diagnostics construct images using the level of contrast between healthy and malignant tissue, which amounts to several percent and less, in case of impedance diagnostics the electrical conductivity of such tissues might amount to several hundreds of percent. This phenomenon is used in detection and localization of tumours and other breast disease.

2. What is impedance?

It is a physical value, which characterizes the electrical resistance of the system (from Latin impedire — "to cause hindrance". Electrical impedance is a total resistance of the electrical circuit to the alternative current passing through it. In general, it is a geometrical sum of active resistance of the electrical circuit and reactive resistance (reactance), measured in Om.

3. What parameters of electrical current can be used in medicine, and in mammology in particular?

In medical diagnostics, particularly in electroimpedance mammography, the alternative current of a rather high frequency is used (as a rule, over 1 kHz). Due to high polarization degree of the intercellular membranes and the working electrodes electrical conductivity, measurements of biological systems, using direct current, is extremely difficult. The permissible value of the current is limited by its biological impact on the cells of living tissue; the former grows with the frequency increase. The current used for scanning in the electroimpedance computer mammography “MEIK”® (5th version) is within the range of 0,5 mA, frequency 50 kHz. These parameters of the measurement systems are absolutely harmless for patients.

4. What are the outlooks for utilizing the multi-frequency scanning?

We studied possibilities of the multi-frequency scanning for visualization of mammary tumor. ("Electro-impedance mammography testing at some physiological woman's periods". A.Karpov, O.Trochanova, XI international conference on electrical bio-impedance. Oslo, Norway, 2001; □Changes in electrical conductivity of mammary gland at multi-frequency measurement□, A.Karpov, O.Trochanova, XVIII scientific and practical conference. Yaroslavl, 2001). But application of the current with frequency within the range of β- dispersion (10^2 □ 10^8 Hz) for breast scanning failed to bring the expected results. The 5th version of □MEIK□ comprises this possibility. We recommend using it only as a tool for research only.

5. How painful is the examination?

The examination, being absolutely painless during the diagnostics and after it, lasts about 30 seconds.

6. What are the indications for impedance mammography?

The electrical impedance can be utilized in the whole range of the breast diseases, namely: benign and malignant neoplasms, mastopathies, mastitis and so on. In addition electrical impedance can be used for dynamic monitoring of women, comprising a risk group, in order to check efficiency of treatment. The examination, done with the help of MIEK during pregnancy as well as after birth, supplies doctors with valuable information concerning particulars of lactation period. This method of screening is widely used for women who take oral contraceptives and undergo substitutive hormonotherapy in climacterical stages.

7. Do any contraindications exist for using the method of impedance mammography?

Impedance mammography is absolutely harmless for a human being; this is why it can be used at any age period, inclusive lactation and pregnancy.

8. How often can impedance mammography be used?

The examination can be used without time limitations, since it is not accompanied by any radiation exposure and is safe for patients. The examination can be carried out when recommended by the physician at any time intervals. It can be used during a menstrual cycle in order to define breast functional particulars (so called dynamic mammography). In perimenopause it should be done at least one a year.

9. Who should conduct the examination in question?

The examination, connected with impedance mammography, should be performed by doctors, familiar with breast anatomy, physiology and pathology, namely: mammologists, obstetricians, or specialists in radiodiagnostics. When carrying out the examination it is preferable to have a nurse□s assistance, since it speeds up the procedure and increases efficiency.

10. Is it possible to diagnose breast malignant growth?

Due to the difference in electrical conductivity of malignant and healthy tissues existing from the initial stage of the tumour process, the device is capable of performing early detection of the oncology pathologies.

11. What minimal size of a tumour can be detected with the help of impedance mammography?

According to the existing statistic data the smallest detected tumours were 3-5 mm.

12. What are the operational characteristics of impedance mammography (sensitivity, specificity, etc)?

Sensitivity amounts to.92%, specificity-.99%, prognostication of positive - 73%, prognostication of negative result - 99%.

13. What method should be used for detection of malignant diseases? — for benign diseases?

It is not correct to discuss preferences any method in detecting any disease. There are no 100% results in diagnostics either in case of benign or malignant diseases of breast anywhere in the world. When choosing the appropriate method one should be guided by the criteria of safety and appropriateness. Taking into account high degree of sensitivity and specificity of the impedance mammography and at the same time its absolute safety, we can recommend starting examination with this method in particular. It case of necessity a more detailed examination can be recommended.

14. Is it recommendable to use the method in question for screening purposes?

The method of impedance mammography meets all demands of screening: safety, affordability, comprehensiveness; it can be performed within a short period of time in a room with limited sizes.

15. Does impedance mammography examination require any special condition?

The impedance mammography doesn□t need any special procedures. The examination is carried out at a room temperature, in rooms with average humidity. The patient takes a lying position on the examination couch.

16. How long does the examination last?

The length of examination procedure is 30 - 35 seconds. The process of diagnostic examination from the moment of obtaining the case history to establishing a conclusion amounts to 15 minutes. Screening examination lasts about 5 minutes.

What is the cost of the examination procedure?

When comparing the cost of various equipment, utilized for the same purposes, it is possible to say that the examination in question is cheaper than X-ray mammography and ultrasound examination.

Can the impedance mammography provoke any complications?

We have never witnessed any complications after impedance mammography.

Electrical Impedance Tomography

Fact from history...

The electrical impedance tomography is the technology of obtaining an image in a body cross-section via non-invasive electrical probing, calculations and algorithms for reconstruction of the impedance distribution. Since different tissues possess different impedance and we are able to differentiate their image, there is a possibility to detect physiological deviations.

The first impedance image was obtained in 1978 by R.P. Henderson and J.G. Webster (fig. 1). Although the image of the chest area was transthoracic, it was not tomographic.

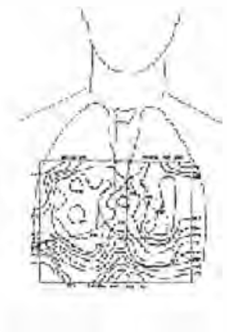


Figure 1. Chest impedance image, obtained by R.P. Henderson and J.G. Webster.

The first electrical impedance tomographic image was obtained by Brian H. Brown and D.C. Barber in 1982 (Sheffield, Great Britain). It was a tomographic image of a forearm (fig. 2).

Figure 2. The electroimpedance image of a forearm clearly displays the ulnar bone and the spoke bone as well as the peripheral adipose tissue

Present days...

Since beginning of the 90s the electrical impedance tomography turned into intensively developing field of research. Dozens of research groups all over the world are involved in experiments connected with it. The largest number of such teams can be found in the Western Europe, first of all, Great Britain, Germany, France and the USA. The following teams of scientists have achieved significant results in medical application of electrical impedance tomography: a) the team, headed by B.H. Brown — in the field of neonatology and oncology; b) the team, headed by D.S. Holder — in the field of neurophysiology; c) the team, headed by I. Frerichs — in the field of pulmonology; d) the team, headed by P.J. Riu — in the field of lung physiology; e) the team, headed by A. Hartov, J. Newell and D. Isaacson — in the field of oncology.

The works on development of electrical impedance tomography started in Russia from the middle of the 90s of the last century in the laboratory for computer physics by a group of scientists from the Institute of Radiotechnology and Electronics of the Russian Academy of Science, headed by Professor, Doctor of Science (Physics and Mathematics) Cherepenin V.A. Within a short time the team achieved results of international level in development of measuring equipment as well as in development of the algorithms for image reconstruction. The medical application have been successfully developed by the head of the perinatal diagnostics department of the Clinical Hospital # 9 in Yaroslavl Karpov

A.Yu., who is author of scientific works in the filed of lung physiology, neonatology, oncology, mammology. The results of the medical research in the field of electrical impedance tomography are available in the reports and proceedings of the International Conferences held in Barcelona (1998), in Oslo (2001), in Gdansk (2004) and Grats (2007).

What is electrical impedance tomography...

In order to obtain the image alternative current is injected into the body via the electrodes, placed around it; then synchro-boundery potentials are computed. All this allows obtaining the aggregate of the impedance distribution data, which via processor, utilising a recovery algorithm, create the impedance computer tomographic image. The principle of the impedance tomography is represented by the following diagram.

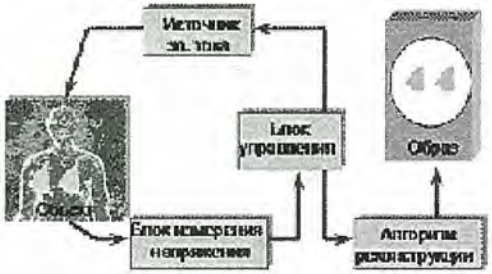


Figure 3. The principle diagram of the impedance tomography

The current, running through the media, creates a volumetric distribution of the electrical potential (voltages). The potential decreases along the current line, moving away from the active electrode (which is injecting the current). The voltage drop per unit of length (electric field intensity) is proportional to the current volume and the media resistance according to the Ohm's law. Measuring voltage drop and knowing the current value, it is possible to calculate the resistance volume. Thanks to the algorithm of reconstruction, it is possible to calculate spatial distribution of resistivity (or electrical conductivity) inside the body, utilising only the voltages, measured on the body□s surface.

The first algorithms of reconstruction of the electrical impedance image, and even all earlier obtained images in vivo, used the recovery algorithm — "back-projection", designed by D.C. Barber. This algorithm was later adopted in the method of computer tomography. In fact computer tomographic images are generated with the help of "back-projection" computation, obtained in projection of the X-rays along the constant lines, defined by the design value of every dot; then a simple image is received after a simultaneous summation.

In the electrical impedance tomography a peripheral profile is a measured electrical voltage between the two adjacent electrodes for every pair of current electrodes. This is the profile relationally back-projected in the region between the equipotential lines. Any distribution of electrical conductivity in the region, limited by two equipotential lines, correlates with the difference of electrical voltage between the electrodes along the normed lines. Distribution of electrical conductivity between two equipotential lines is proportional to the gradient of the electrical voltage of the corresponding limits.

There exist several methods for generation of the electrical impedance images, which fall into two categories: static image and differential image. The static image consists of the image of an absolute distribution of impedance inside some part of a body, in other words, an anatomical image of the scanned area is being formed as a result. The differential or dynamic image consists of generating an image of electroconductivity changes between two sets of measurements.

Electrical properties of biological tissues...

A living organism does not only generate bioelectricity, but passively conducts the current, which occurs in it or is applied from outside. Biological objects, being complicated systems, are characterised by availability of numerous interfaces. Various membranes, which from the molecular viewpoint can be treated as practically infinite two-dimensional surfaces, play this function in an organism. In the space, which surrounds the cell membranes, the electrical conductivity is explained by presence in it of ions, moving polar molecules and isolators. Electrical properties of chemical compositions are defined by a number of characteristics, the main of them are: polarity, the charge□s sign and value, molecular weight, mobility and elementary composition. Inside the cells ions of potassium and organic anions are main free charges, outside — ions of sodium and chlorine. Electrical conductivity of biological fluids is proportional to content of free ions. High-molecular substances, which movement under influence of the electric field is impeded, large ions with low mobility affect the value of electrical conductivity of a biological object, although to a smaller degree. The abovementioned compositions form, the so called, active component of electrical conductivity of resistance. In accordance with the Ohm law, the substance resistance is proportional to the drop of the applied voltage while the electric current passes through the investigated substance.

R (resistance) = E/I, where: R = resistance (□m); E = applied voltage (volts); I = current intensity (amperes).

On the border of the phases division, each of which contains charged ions or dipole molecules, the polarization effect with formation of a double electric layer is created, which generates a potential difference on the phases division. The cell membranes, which are interfaces in a biological object, form the reactive component of electrical conductivity or reactance. (figure 4). Reactance (impedance), defined in description of biological tissues as capacitive resistance, counteraction to the instantaneous flow of electrical current via permittance (capacitance). Mathematically, reactance is expressed by the follow equation for an alternating-current circuit:

Reactance = $1/2\pi*F*C$, where: reactance = impedance (Om); F - voltage frequency (Hertz); C - capacitance (farad); π = 3.1428.

The above equation demonstrates that reactance forms an inverse ratio with the current frequency and capacitance. Hence, with frequency of the current increasing, reactance decreases. At extremely low values of frequencies reactance is infinite.

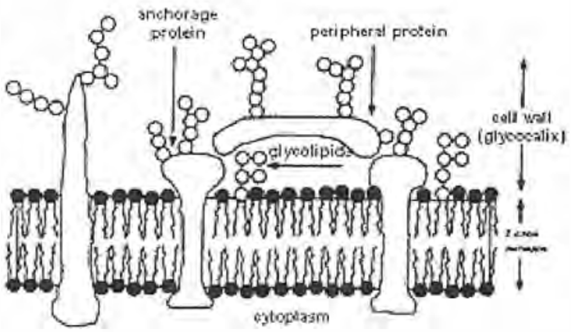


Figure 4. Structure of a cell membrane.

In a healthy body a cell membrane consists of a nonconductive layer, comprising lipids and protein molecules (fig. 4). Under the impact of alternative current the cell membrane structure changes reactive capacity of the elements, which act as capacitors. Biologically, a cell membrane is a selective semipermeable barrier, dividing the intracellular and extracellular space. It protects the interior of the cell, enabling penetration of certain substances for which it is permeable. The cell membrane preserves the osmotic pressure and the ions gradient of concentration between the intracellular and extracellular spaces. This gradient creates the difference of the electric potential, required for the cell survival. The damage of a cell membrane as well as its functions is lethal for the cell the same way as the cell nucleus damage is.

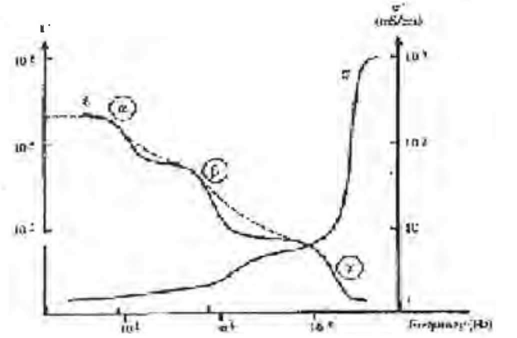


Figure 5. Dependence of dielectric capacitivity and electrical conductivity of biological tissues from the current frequency

Due to high polarization degree of the intercellular membranes and the electrodes, electrical conductivity measurements of biological systems, using direct current, is extremely difficult. At low frequencies of alternative current the larger amount of it flows along the intercellular spaces. When the current frequency increases, reactance of a capacity decreases, polarization phenomena reduce. Dependence of resistance and the object capacity on frequency has been called dispersion (fig. 5). At high frequencies total resistance of the system depends only on active resistance of intercellular spaces and cytoplasm.

Concerning safety...

On the whole, in the course of examination the measurement of biological impedance requires the electric current to be passed through biological tissue. Naturally, it might have harmful or detrimental effect on some tissue. From the

72

physiological point of view we do not mean tissue excitation as in the case of stimulation.

There are three questions to be dealt with:

- what kind of current should be considered adequate?
- what are acceptable values of the injected current?
- what is acceptable values of the injected current frequency?

The flow of direct, in other words, unidirectional current, through electrolytes, specifically through biological tissue, is accompanied by irreversible chemical reactions at the electrodes, via which the object is connected with the exterior part of the electric circuit. Due to this fact in medical diagnostics only alternative current is used with rather high frequencies (as a rule, exceeding 1 kHz).

The permissible value of current is limited by it biological impact and increases with the growth of the currency frequency. The figure 6 sums up the main effects of electrical current. At weak stimulation (about 0,3 — 10 mA) only tactile sensation are registered. At wide ranges (10 — 100 mA) the nerves and muscles are subjected to strong stimulation resulting in contraction, pain and fatigue. The values of current exceeding 15 mA, depending on the way of its flow, can cause respiratory arrest, noticeable fatigue and intensive pain. The fibrillation zone is represented on the figure by the range between 50 mA and 5 or 6 A. Higher values of current might cause prolonged contraction of cardiac muscle (contracture) and\or heavy burns.

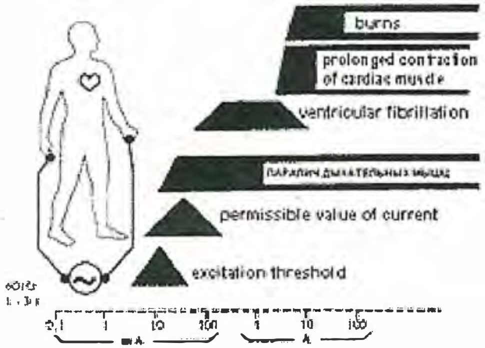


Figure 6: Additive effect of low frequency current (60 Hz): two copper leads are held by a man weighing about 70 kg; the arms are raised, exposition 1 and 3 seconds.

Application of electricity at any part of skin leads to stimulation of various receptors of derma. The worst effects are caused by the frequencies below 300 Hertz with tendencies to minimum between 10 and 100 Hertz. This knowledge is important in cardiovascular physiology, cardiology and hospital electrical safety. The value of the electrical current, used for biological impedance research, must always be below the safe threshold of the current intensity — time on the irritability curve of the tissue, through which the current flows.

Alternative current frequency	Maximum amplitude of current
< 1 kHz	0.1 mA
1 - 100 kHz	0.1*f mA, where f - is frequency (kHz)
> 100 kHz	10 mA

Chart 1. Permissible amplitude of electrical current used for diagnostic purposes.

Sickness Statistics

Breast cancer is the most frequent causes of deaths of women, compared with other forms of malignant neoplasms. Denmark, Ireland and the Netherlands lead in respect of mortality caused by cancer. Russia comes 28th in this list. . In the countries of Western Europe and North America breast cancer is a leading cause of deaths among women of 35 — 54 years of age (20%), and in women after 55 it comes second after cardiovascular diseases.

Country	Sickness rate	Death rate
Austria	59,0	22,2
Belgium	79,2	26,7
Denmark	73,2	26,9
Finland	64,7	17,2
France	58,2	19,7
Germany	65,6	21,8
Greece	40,6	15,0
Ireland	67,2	25,5
Italy	53,7	20,6
Luxembourg	72,0	27,3
The Netherlands	81,0	26,8
Portugal	49,9	18,2
Spain	46,2	17,2
Sweden	72,8	17,8
England	68,1	28,2
European Union	60,9	21,8

Breast cancer sickness rate and death rate in the countries of the European Community in 1996, (per 100 000)

The average age of women suffering from breast cancer (58,3 years) is below women, with other forms of neoplasms, exclusive of malignant neoplasms of bones, soft tissues, nervous system, thyroid gland, placenta, skin melanomas, hemoblastosis. The dynamics of sickness and death rate feature a certain tendency to "aging" of women suffering from breast cancer. The growth rates of age indices of morbidity is especially pronounced in the age group of 50 — 59 years of age (40,3%) as well as 70 years and over (59,4%).

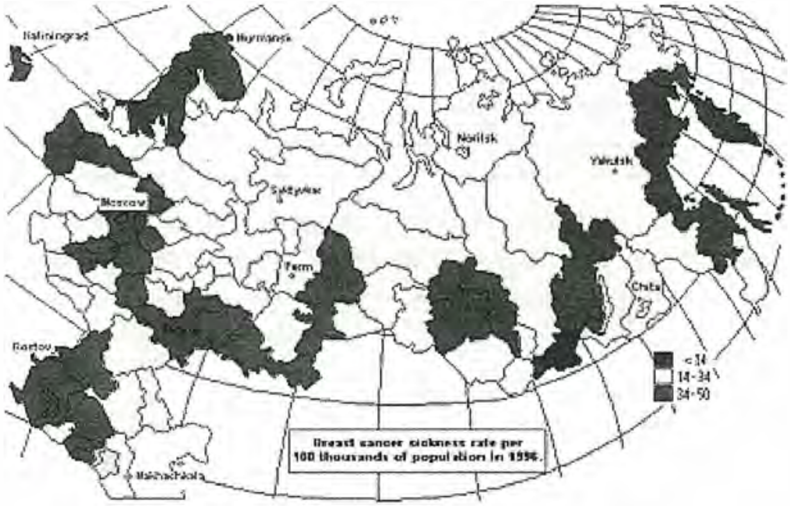
Age	Morbidity growth rate	Death growth rate
Before 30	0,0	-33,3
30-39	5,3	9,7
40-49	12,5	20,3
50-59	40,3	38,8
60-69	25,1	31,7
70 and over	59,4	57,9

On the territory of Russia the highest sickness rate of breast cancer in 1996 was registered in the North-western (43,2) and Central (38,6) economic zones, the lowest in Volgo-Viatksiy zone (28,7).

Economic region	Morbidity	Death rate
Northern	30,4	13,4
North-western	43,2	20,3
Central	38,6	18,3
Volgo-Viatksiy	28,7	13,1
Central-Chernozem	32,4	14,6
Volga	33,8	15,6
North-Caucasian	33,4	16,7
Urals	32,6	14,6
Western Siberian	34,5	16,1
Eastern Siberian	31,0	16,2
Far-Eastern	35,4	17,5

Kaliningrad region	33,0	16,1

Among the total number of malignant neoplasms in Russian women, breast cancer comes first (18,3% of all cancer patients). With the death rate being 50%, the number of patients suffering from breast cancer increases up to 40 thousand cases per year. Compared to the data of 1980 the death rate from breast cancer increased by 72% and reached in 2001 19,6 thousand cases in Russia.



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